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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,767	02/26/2001	David Edwin Thurston	65435-9002	6332

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/23/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/763,767

Applicant(s)
THURSTON et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 5 6) ☐ Other:

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DETAILED ACTION

Claims 1-45 are pending in the application.

Priority

1. Any non-provisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross - references to other related applications may be made when appropriate.

“This application is a national stage entry under 35 U.S.C. § 371 of PCT/GB99/02838, filed August 27, 1999.” is suggested.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "figure 24" has been used to designate both the figure on page 24/32 and the figure on page 26/32. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Specification

3. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as **section headings**. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) **Brief Description of the Several Views of the Drawing(s).**
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reasons apply:

- a) There is no definition in the specification for the myriad of possible heterocyclic groups in the definition of R as claimed herein. The aryl moiety which is defined for the substituent R in the claims is opened ended and reads on all such rings and ring systems of which are neither supported nor contemplated. *In re Lund 153 USPQ 625*.
- b) There is no definition in the specification for “functional group” which is open ended. The instant claim language indicates that R may optionally contain on or more hetero atoms, which may form part of, or be, “a functional group”. There is no definition in the specification for what possible functional groups this includes nor what is meant by “functional group”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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- a) Claims 1-44 are vague and indefinite in that it is not known what is meant by "a conjugated system" in the definition of R.
- b) Claims 1-6, 11, 13, 14, 20, 21, 24-27 and 38-44 are vague and indefinite in that it is not known what is meant by the moiety $-O-CH_2)_p-O-$ in the definition of R_7 and R_8 when taken together.
- c) Claim 2 recites the limitation " COR^C , $CONH_2$, $CONHR^C$, $CONR^C_2$, cyano or phosphonate" in the definition of R^A and R^B . There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 4 recites the limitation " CH_2OR " in the definition of R_2 . There is insufficient antecedent basis for this limitation in the claim.
- e) Claim 5 recites the limitation " CH_2OAc " in the definition of R_2 . There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 6 recites the limitation "conjugated system with the double bond of the C-ring" in the definition of R_2 . There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 12 recites the limitation "1 to 12" in the definition of p. There is insufficient antecedent basis for this limitation in the claim.
- h) Claim 13 recites the limitation "sibirosamine pyranoside" in the proviso labeled (i). There is insufficient antecedent basis for this limitation in the claim.

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- i) Claim 16 is vague and indefinite in that the definition of R₆, R₇, R₉ and R₈ are not stated as a Markush group. R₆, R₇, R₉ and R₈ are independently selected from H, OMe and OCH₂Ph, **and** I. It is not known what is meant by the second occurrence of "and".
- j) Claim 19 recites the limitation "1 to 12" in the definition of p. There is insufficient antecedent basis for this limitation in the claim.
- k) Claim 24 recites the limitation "a dimer" in the definition of R₆, R₇, R₈ and R₉. There is insufficient antecedent basis for this limitation in the claim.
- l) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. Claims are pending in the application.. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. Claims are pending in the application.. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. Claims are

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pending in the application.. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd.

Claims are pending in the application.. 1949). In the present instance, claim 25 recites the broad recitation aryl group, and the claim also recites preferably of up to 12 carbon atoms which is the narrower statement of the range/limitation.

- m) Claim 28 recites the limitation "1 to 12" in the definition of p. There is insufficient antecedent basis for this limitation in the claim.
- n) Claim 30 recites the limitation "nitrogen protecting group" in the definition of R'₈ and R''₈. There is insufficient antecedent basis for this limitation in the claim.
- o) Claim 31 recites the limitation "electron withdrawing group" in the definition of R₇. There is insufficient antecedent basis for this limitation in the claim.
- p) Claim 36 recites the limitation "optionally substituted by one or more halo, hydroxy, amino, or nitro groups" in the definition of R. There is insufficient antecedent basis for this limitation in the claim.
- q) Claims 38 and 40-43 provides for the use of the compounds of formulae Ia, Ib, II, III and IV, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
- r) Claims 43 and 44 are vague and indefinite in that it is not known what is meant by cisplatin-**refactory** disease.

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- s) Claim 45 recites the limitation "SJG 136" in the method according to claim 44.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 38 and 40-43 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 20 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by

Takanabe et al., U.S. 4,185,016. Takanabe teaches the compounds, compositions and method of

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use of the compounds of formula III where R_6 and R_7 are hydrogen, R_8 is hydrogen, methyl or methoxy and R_9 is hydroxy or acetoxy. See column 3, lines 5-14 and examples 9, 10, 19, 20, 31, 32, etc.

8. Claims 13-15, 17 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Arima et al., GB 1 299 198. Arima teaches the compounds, compositions and method of use of the compounds of formula II where R'_2 is CH-Me, R_6 and R_7 are hydrogen, R_8 is 4-bromobenzoyloxy and R_9 is hydrogen. See example 5.

9. Claims 13-15, 17 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujisawa Pharmaceutical Company, JP 57 131791. JP '791 teaches the compounds, compositions and method of use of the compounds of formula II where R'_2 is O, R_6 is hydrogen, R_7 is methoxy, R_8 is hydroxy and R_9 is hydrogen.

10. Claims 20, 38-40 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neil et al., Synlett. O'Neil teaches the compounds, compositions and method of use of the compounds of formula III where R_6 is hydrogen, chloro or iodo, R_7 is hydrogen or chloro, R_8 is hydrogen, chloro, $CH_2=CH$, iodo or bromo and R_9 is hydrogen. See examples 2, 3, 4,, 6, 7, 8, etc.

11. Claims 1, 11 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Umezawa et al., JP 53-82792. JP '82792 teaches the compounds, compositions and method of

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use of the compounds of formula Ia where R_6 and R_7 are hydrogen, R_8 is methyl, R_9 is hydroxy, -
A- R_2 is $-\text{CH}=\text{CH}-\text{C}(=\text{O})-\text{NH}(\text{CH}_3)$. See formula II on page 887.

12. Claims 13-19 and 38-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Gregson et al., Chem. Commun. Gregson teaches the compounds, compositions and method of use of the compounds of formula II where R_6 is hydrogen, R_7 is methoxy, R_8 forms the dimer through the bridge $-\text{O}-(\text{CH}_2)_3-\text{O}-$, R_9 is hydrogen, and R'_2 is CH_2 . See example 1.

13. Claims 20, 25-27 and 38-44 are rejected under 35 U.S.C. 102(a) as being anticipated by O'Neil et al., Tetrahedron Letters. O'Neil teaches the compounds, compositions and method of use of the compounds of formula III where R_6 is hydrogen or chloro, R_7 is hydrogen or fluoro, R_8 is hydrogen, fluoro, chloro, thien-2-yl, furan-2-yl or phenyl and R_9 is hydrogen. See examples 1, 2, 3, 4, 5, 6, 7, 8, etc.

14. Claims 20, 25-27 and 38-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Guiotto et al., Bioorganic & Medicinal Chemistry Letters. Guiotto teaches the compounds, compositions and method of use of the compounds of formula III where R_6 is hydrogen, R_7 is phenyl, 4-methylphenyl, 4-fluorophenyl, 3-nitrophenyl, 2-methoxyphenyl or 4-methoxyphenyl, R_8 is hydrogen, R_9 is hydrogen. See examples 4a, 4b, 4c, 4d, 4e, 4f, etc.

15. Claims 1, 7, 11, 20, 22 and 38-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Thurston et al., Journal of Medicinal Chemistry. Thurston teaches the compounds,

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compositions and method of use of the compounds of formulae Ia and III where R_6 is hydrogen, R_7 is sugar-O-, hydroxy, or methoxy, R_8 is hydroxy, methoxy, $-O-CH_2-CH_2-COOCH_3$, $-O-(CH_2)_3-OCH_2Ph$ or $-NH-COOCH_2Ph$ and R_7 and R_8 together form a $-O-(CH_2)_2-O-$ or $-O-CH_2-O-$ moiety, R_9 is hydrogen or methoxy, and $-A-R_2$ is $-CH=CH-CH_3$. See examples 3, 16a, 16b, 20, 23, 29, 53, etc.

16. Claims 13-18, 20, 28 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Thurston et al., Chem. Rev. Thurston teaches the compounds, compositions and method of use of the compounds of formulae II and III where R_6 is hydrogen, R_7 is hydrogen or methoxy, R_8 is chloro, benzyloxy or 4-nitrobenzyloxy or R_7 and R_8 together form a $-O-CH_2-O-$ moiety, R_9 is hydrogen and R'_2 is $=CH-CH_3$. See examples 90d, 122d, 156, etc.

17. Claims 1, 11 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunimoto et al., The Journal of Antibiotics. Kunimoto teaches the compounds, compositions and method of use of the compounds of formula Ia where R_6 is hydrogen, R_7 is hydrogen, R_8 is methyl, R_9 is hydroxy and $-A-R_2$ is $-CH=CH-C(=O)-NHCH_3$. See formula IV.

18. Claims 13-18 and 38-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Langley et al., The Journal of Organic Chemistry. Langley teaches the compounds, compositions and method of use of the compounds of formula II where R_6 is hydrogen, R_7 is methoxy, R_8 is benzyloxy, R_9 is hydrogen and R'_2 is $=CH-CH_3$. See example 2b.

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19. Claims 20, 38-40 and 42-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Baraldi et al., Bioorganic & Medicinal Chemistry Letters. Baraldi teaches the compounds, compositions and method of use of the compounds of formula III where R_6 is hydrogen, R_7 is methoxy, R_8 is $-O-(CH_2)_2-C(=O)-OCH_3$ and R_9 is hydrogen. See example 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 20 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takanabe et al., U.S. 4,185,016. The generic structure of U.S. '016 encompasses the instantly claimed compounds (see Formula II, column 2) and for the same use as claimed herein. Examples 9, 10, 19, 20, 31, 32, etc. differ only in the nature of the R_1 and R_3 substituents. Column 1, lines 62-65 defines the substituent R_1 as a hydrogen atom, alkyl group, hydroxy group or alkoxy group and R_3 as a hydrogen atom or acyl group. Compounds of the instant invention are generically embraced by U.S. '016 in view of the interchange ability of R_1 and R_3 substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example hydroxy or ethoxy for R_1 as well as other possibilities from

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the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

21. Claims 13-15, 17 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al., GB 1 299 198. The generic structure of GB '198 encompasses the instantly claimed compounds (see Formula V, page 4) and for the same use as claimed herein. Example 5 differs only in the nature of the R₁ substituent. Page 9, lines 4-6 defines the substituent R₁ as a hydrogen atom, a C₁-C₆ alkyl, C₁-C₆ alkyl-carbonyl, aryl-C₁-C₆ alkyl-carbonyl or aryl-carbonyl radical. Compounds of the instant invention are generically embraced by GB '198 in view of the interchange ability of the R₁ substituent of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example acetyl or benzoyl for R₁ as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

22. Claims 13-15, 17 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujisawa Pharmaceutical Company, JP 57-131791. The generic structure of JP '791 encompasses the instantly claimed compounds (see Formula I) and for the same use as claimed herein. The 8-hydroxy-7-methoxy-1H-pyrrolo[2,1-c][1,4]benzodiazepine-2,5(3H,11aH)-dione example anticipated above differs only in the nature of the R¹ and R² substituents. The substituent R¹ is defined as a hydroxy group and R² is defined as an alkoxy group. Compounds of the instant

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invention are generically embraced by JP '791 in view of the interchange ability of the R¹ and R² substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example ethoxy or *i*-propoxy for R² as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

23. Claims 20-23 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langlois et al., FR 2 256 683. The generic structure of FR '683 encompasses the instantly claimed compounds (see Formulae I and III, pages 1 and 3 respectively) and for the same use as claimed herein. The examples differ only in the nature of the R₁, R₂, R₃, R₄, R₅, R₆ and R₇ substituents. Page 33, lines 4-19 defines the substituent R₁ and R₂ are chalcogen or independently hydrogen, hydroxy, alkoxy or alkanoyl, R₃, R₄ and R₅ are hydrogen, halo, hydroxy, alkoxy, alkanoyl or any two of them OCH₂O and R₆ and R₇ together form a double bond. Compounds of the instant invention are generically embraced by FR '683 in view of the interchange ability of R₁, R₂, R₃, R₄, R₅, R₆ and R₇ substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example OCH₂O as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

24. Claims 1, 7-11 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langlois et al., WO92/19620. The generic structure of WO '19620 encompasses the instantly

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claimed compounds (see Formula I, page 1) and for the same use as claimed herein. The 3-(5,11a-dihydro-5-oxo-1H-pyrrolo[2,1-c][1,4]benzodiazepin-2-yl)-N,N-dimethyl-2-propenamide example which is excluded by proviso differs only in the nature of the R₁, R₂, R₃, R₄, X, Y, Z and n substituents. The substituents R₁, R₂ and R₃ are defined as hydrogen, halo, hydroxy, alkoxy, alkanoyl or any two of them OCH₂O, R₄ and X together form a double bond, n is 1 or 2 and Y and Z are identical or different and are a hydrogen atom, alkyl radical, alkoxycarbonyl, aminocarbonyl, N-alkyl or N,N-dialkylaminocarbonyl, cyano or phosphonate. Compounds of the instant invention are generically embraced by WO '19620 in view of the interchange ability of the R₁, R₂, R₃, R₄, X, Y, Z and n substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example ethoxy or *i*-propoxy for R² as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

25. Claims 20-24, 28 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurston et al., WO 93/18045. The generic structure of WO '18045 encompasses the instantly claimed compounds (see Formula I, page 3) and for the same use as claimed herein. Example 10 differs only in the nature of the R¹ and X substituents plus the additional substituents in one or more of the 1, 2, 3, 6, 7, 9 and 11-positions. Page 3 defines the substituent X as -O-, -S- or -NH- and R¹ as an alkylene chain containing from 3 to 12 carbon atoms, which chain may, if

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desired, be interrupted by one or more heteroatoms, and which chain may, if desired, contain one or more carbon-carbon double or triple bonds. Compounds of the instant invention are generically embraced by WO '18045 in view of the interchange ability of R¹ and X substituents plus the additional substituents in one or more of the 1, 2, 3, 6, 7, 9 and 11-positions of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example OCH₂CH₃ or hydroxy as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No.

09/763,813. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the compounds of the instant invention are embraced by the library of U.S.S.N 09/763,813.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. Claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/763,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant invention are embraced by the library of U.S.S.N 09/763,768.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/763,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the instant invention are embraced by the library of U.S.S.N 09/763,814.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim Objections

29. Claims 6-12, 19, 25-28, 32-45 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to the claims from which they depend in the alternative and a multiple dependent claim cannot depend on another multiple dependent claim.

See MPEP § 608.01(n).

37 CFR 1.75. Claim(s).


(c) one or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. **Any dependent claim which refers to more than one other claim (multiple dependent claim) shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim.** For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes, also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(d). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

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The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
May 22, 2002